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IN THE

Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF AARP, NATIONAL WOMEN'S HEALTH NETWORK, U.S. PUBLIC INTEREST RESEARCH GROUP, AND NATIONAL RESEARCH CENTER FOR WOMEN & FAMILIES AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments of 1976, which amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

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INTEREST OF *AMICI CURIAE*[1]

AARP is a non-profit, non-partisan organization with more than 39 million members, dedicated to addressing the needs and interests of people aged 50 and older. It promotes independence, dignity, and purpose for older persons; sponsors research on aging; provides educational programs, publications, and member benefits; and represents the concerns of older persons before government bodies. As the largest membership organization representing the interests of older persons, AARP has long supported laws and public policies designed to protect its members' rights and to preserve the availability of legal redress when they are harmed in the marketplace.

The National Women's Health Network improves the health of all women by influencing policy and supporting informed consumer decision-making. The Network is supported by 8,000 individual and organizational members and accepts no financial support from pharmaceutical companies, tobacco companies, or device manufacturers. Since it was founded in 1975, the Network has worked to ensure that safe drugs, devices, and medical procedures are available to all women. The Network believes that effective state tort law remedies are necessary to protect women from dangerous medical devices.

U.S. Public Interest Research Group ("U.S. PIRG"), the federation of state Public Interest Research Groups, is a national, non-profit advocacy group with more than one million members around the country. Its mission is to protect the interests of consumers and ordinary citizens using the tools of investigative research, media reports, grassroots organizing, legislative and public policy advocacy, and litigation. The ability of States to protect the

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that they authored this brief and that no entity other than *amici*, their counsel, or their members made a monetary contribution to its preparation or submission. All parties have consented to the filing of this *amici* brief, and letters reflecting their blanket consent to the filing of *amicus* briefs in this case are on file with the Clerk.

health and well-being of their residents has been a long-standing area of concern to U.S. PIRG.

The National Research Center for Women & Families is a non-profit, nonpartisan organization dedicated to improving the health and safety of women, children, and families, by using objective, research-based information to encourage new, more effective programs and policies. The Center gathers and analyzes information and translates it into clearly presented facts and policy implications that are made widely available to the public, the media, and policy makers.

Amici have participated as an *amicus curiae* in numerous cases opposing federal preemption of state and local laws that provide important consumer protections.

BACKGROUND

"To provide for the safety and effectiveness of medical devices intended for human use," Congress enacted the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 ("MDA"). *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996); *id.* at 491 (Stevens, J., plurality) ("[T]he primary issue motivating the MDA's enactment [was] the safety of those who use medical devices.").

Before 1976, the federal Food and Drug Administration ("FDA") could regulate drugs, but not medical devices. A series of high-profile failures of medical devices, most notably the Dalkon Shield, a defective intrauterine device responsible for at least 18 deaths and thousands of serious injuries, led to calls for increased consumer protection against such dangerous devices. *See* S. Rep. No. 94-33, at 1-2 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1070-71.[2] In response, Congress passed the MDA, which provided the FDA with limited new authority over the medical device industry. Among other provisions, the MDA created

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[2] *See also* Morton Mintz, *Questions Arose Early on Contraceptive's Safety*, Wash. Post, Apr. 7, 1985, at A1 (describing how defects in the Dalkon Shield's design caused infections in thousands of women and birth defects in their children).

a premarket approval ("PMA") process designed to prevent dangerous medical devices from reaching the market. *See* Pub. L. No. 94-295, § 2, 90 Stat. 552 (codified as amended at 21 U.S.C. § 360e).

This PMA process is part of a three-tiered regime that provides general regulation of the "vast array of medical equipment [f]rom bedpans to brainscans," *Lohr*, 518 U.S. at 476 (alteration in original; internal quotation marks and citation omitted). The MDA requires that the FDA classify every medical device into one of three categories. Class I devices, like rubber gloves, are the least risky devices and are subject to only basic requirements, such as that the device not be misbranded or adulterated. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices, such as hearing aids, are more likely to harm consumers, so the FDA may pass regulations subjecting these devices to additional controls, such as requiring specific warning labels. *See id.* § 360c(a)(1)(B); 21 C.F.R. § 801.430. In most cases, manufacturers do not need to obtain approval from the FDA before marketing Class I or Class II medical devices to consumers.[4]

A Class III medical device, like the balloon catheter at issue in this case, is one that either presents "a potential unreasonable risk of illness or injury" or is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Before manufacturers can market these devices, they must receive permission from the FDA, through either the premarket notification or the premarket approval process. The premarket notification process requires the manufacturer to submit a form to the FDA describing the device and explaining how it is substantially equivalent to an FDA-approved device that is already on the market. *See id.* §§ 360c(f)(1)(a),

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[4] *See* FDA, *Medical Device Exemptions 510(k) and GMP Requirements*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm (last visited Aug. 23, 2007).

360e(b)(1)(B); 21 C.F.R. § 807.92. If the FDA finds, on the basis of this information, that the device is substantially equivalent to an approved device, it can be marketed. *See Lohr*, 518 U.S. at 478-79.

If no substantial equivalent exists, the device can be sold only upon the FDA's premarket approval, which requires a more detailed application from the manufacturer and a lengthier review of that application by the FDA. *See* 21 C.F.R. § 814.20. In *Lohr*, this Court held that premarket notification does not preempt duties traditionally enforced by state tort law. *See* 518 U.S. at 501-02. This case involves the preemptive effect of the second Class III approval process, the PMA.

The MDA includes a narrow, express preemption provision that, "with respect to a device intended for human use," preempts a state "requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). FDA regulations implementing § 360k(a) provide that an FDA requirement has preemptive effect only when it establishes a device-specific "counterpart" to a "divergent" state-law requirement that is "specific" to a particular device. 21 C.F.R. § 808.1(d). The MDA does not preempt requirements of "general applicability . . . to other products." *Id.*

For example, FDA regulations impose specific design requirements for certain laser devices, *see id.* § 886.4392, which would preempt contrary or additional state regulation. The FDA may also exempt state requirements from the preemptive effect of a federal requirement, *see* 21 U.S.C. § 360k(b), and the exemptions granted reflect the FDA's narrow understanding of § 360k(a)'s preemptive effect. What this Court recognized in *Lohr* remains true today: "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability; all 22

existing exemptions apply to excruciatingly specific state requirements regarding the sale of hearing aids." 518 U.S. at 499-500; *see* 21 C.F.R. §§ 808.53-808.101.

SUMMARY OF ARGUMENT

I. Congress enacted the MDA to prevent manufacturers from introducing new, untested, and potentially dangerous medical devices to doctors and patients, not to provide a comprehensive safeguard from defective products. While it requires device makers to conduct some testing and to provide a "reasonable assurance" of product safety, the PMA process is based on limited information, which restricts its depth and scope. The FDA does not routinely require controlled clinical trials, is unable to subpoena information from manufacturers, has no authority or resources to conduct independent testing, and cannot compare the safety or efficacy of a submitted device to others on the market. Furthermore, PMA applications enjoy a presumption in favor of approval; if an enumerated reason for denial does not apply, the statute and implementing regulations require premarket approval.

This limited premarket review is a one-time licensing scheme and involves very little continuing regulation after a device is approved and in use by doctors and patients. Defective devices with premarket approval typically remain on the market until the manufacturer commences a voluntary recall, and the FDA neither compensates victims nor sanctions device makers.

II. The traditional state tort system provides manufacturers with safety incentives, the public with information about defective devices, and victims with compensation for their injuries. The PMA system, at best, can only supplement—and cannot supplant—those traditional functions of state tort liability. When dangerously defective devices receive premarket approval and injure scores of patients, litigation reinforces the purposes of the MDA—improving the safety and effectiveness of medical devices by uncovering flaws, encouraging compliance with FDA standards, and compensating victims.

Premarket approval is an important process intended to end an era in which manufacturers marketed potentially dangerous medical devices without any meaningful testing and with no assurances of safety. But, while the PMA process provides minimum safeguards, it is insufficient to replace the comprehensive and continuous safety incentives, information disclosure, and victim compensation that state tort law has traditionally provided.

ARGUMENT

I. PREMARKET APPROVAL PROVIDES A LIMITED SCREENING OF MEDICAL DEVICES THAT IS INADEQUATE AND NOT INTENDED TO REPLACE STATE TORT LAW

As this Court recognized in *Lohr*, "the statutory framework" and "the structure and purpose of the statute as a whole," revealed in the text and "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law," are relevant in interpreting the MDA's preemption provision. 518 U.S. at 486 (internal quotation marks and citations omitted). Such a reasoned understanding reveals that the PMA process was established as, and remains, one where "the agency faces limitations that result from many factors, including the agency's legal mandate, pressures from industry, pressures from advocacy groups, funding constraints, and varied political pressures." Richard A. Deyo, *Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice*, 17 J. Am. Board Fam. Prac. 142, 143 (2004).

PMA is based upon partial information that is reviewed by a constrained and conflicted FDA. That review merely screens new Class III medical devices and licenses for market those that appear to meet a generic standard of safety and efficacy. The FDA does not apply a single specific safety standard or requirement to a device before its approval. And PMA is a one-time review, with no reevaluation and very little FDA oversight once a device

reaches doctors and patients. Due to the limitations inherent in the PMA process, the FDA cannot guarantee that defective, dangerous, and deadly medical devices will not reach consumers. The limited PMA process, which was intended to promote consumer safety, is entirely inadequate to replace the long-standing safety incentives and consumer protections provided by state tort law.

A. Premarket Approval Applies A Generic Safety Standard Based On Limited Device Testing Reviewed By Burdened Regulators

1. Limits on the information that manufacturers must submit to the FDA during the PMA process restrict the scope and depth of the FDA's review. A manufacturer's PMA application includes information on the device, any investigations conducted into its safety and efficacy, and its manufacture, processing, and labeling. *See* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The FDA lacks authority to subpoena additional information from the device maker or independently to obtain safety data. *See* Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 Tenn. L. Rev. 1357, 1386 (1994).

Those constraints inhibit the FDA's review. First, the testing of device safety reported in the PMA application can be quite limited, and many applications are approved despite the lack of any controlled clinical study. *See* Scott D. Ramsey et al., *The Limited State of Technology Assessment for Medical Devices: Facing the Issues*, 4 Am. J. Managed Care SP188, SP190 (1998) ("Studies do not necessarily have to be randomized or have a control population, although the FDA encourages controlled clinical investigations. In practice, most new device evaluations are neither randomized nor controlled studies."). Whereas the safety of new *drugs* must be demonstrated by at least two controlled clinical trials, *device* manufacturers need submit only a single clinical study, and controls are not mandatory. *See* Michael D. Green & William B. Shultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 Geo. L.J. 2119, 2136 (2000); *see also* Deyo, 17 J. Am.

Board Fam. Prac. at 144 (recognizing that the FDA's approach to approving medical devices is "less stringent" than that applied to new drug approvals).

Further, that limited clinical testing can be unreliable. As two former editors-in-chief of the *New England Journal of Medicine* have observed, "companies now often insist on controlling how the research is done and reported, and whether the results will even be published at all," under "financial arrangements with academic medical centers and their faculties . . . that threaten the objectivity and credibility of clinical research." Marcia Angell & Arnold S. Relman, Op-Ed, *Prescription for Profit*, Wash. Post, June 20, 2001, at A27. The FDA has no authority to conduct or commission independent investigations into device safety and must typically rely on study results provided in the manufacturer's application.

Second, a PMA application discloses nothing more than the device design, manufacture, and labeling that the manufacturer chooses to submit for approval. *See* 21 U.S.C. § 360e(c)(1). Thus, the manufacturer is not required to submit information about development of the device, including any alternative designs, manufacturing methods, and labeling possibilities that the manufacturer considered, but rejected. Nor does the FDA have the authority to subpoena these and other records from the manufacturer, and, "therefore, in most instances cannot compel the disclosure of information about product risks." Schwartz, 61 Tenn. L. Rev. at 1386.

2. The PMA process applies a generic safety standard; it does not impose device-specific safety requirements demanding particular design, manufacture, or labeling. The FDA merely evaluates whether the manufacturer has provided a "reasonable assurance" that its device meets the general safety standard applicable to *all* medical devices. *See* 21 U.S.C. § 360e(c)(3).

When the FDA determines that a manufacturer has submitted a complete PMA application according to the application criteria, it evaluates the application to deter-

mine whether the device maker has made "a showing of reasonable assurance" that the device is safe and effective. *Id.* § 360e(d)(2)(A), (B). The factors to which the FDA looks in determining safety apply generally to all Class III devices, as well as to the classification decision for any type of medical devices and to the establishment of performance standards for any Class II device. *See* 21 C.F.R. § 860.7. Some consider this generic review to be rigorous because manufacturers devote considerable time to preparing an application and because the FDA takes months to review the application for compliance. But, as the government once argued to this Court, time is no substitute for specificity: the FDA does "not set out specific requirements for the particular device" and, instead, "the manufacturer may select any design, manufacturing, and labeling features that will satisfy the general minimum standards in the Act and regulations." U.S. Amicus Br. at 16, *Smiths Indus. Med. Sys., Inc. v. Kernats*, No. 96-1405, *cert. denied*, 522 U.S. 1044 (1998).[4]

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[4] For more than 25 years after the MDA's enactment, the government opposed PMA preemption, as it did in *Kernats*. As the FDA's former Chief Counsel explained, "[s]ince the passage of the [MDA], it has been the agency's position that the scope of preemption under section 521 should be interpreted narrowly, with a presumption against preemption," and that "preemption is limited to instances where there are *specific* FDA requirements applicable to a particular device or class of devices." Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 7 (1997) (emphasis added). Beginning in 2004, the government reversed course and advocated for preemption in the lower courts. *See, e.g.*, U.S. Amicus Br., *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597). Because preemption analysis turns on congressional intent, it is unpersuasive for the current Administration to purport to have engaged in a 180-degree reassessment of congressional intent after a quarter-century of settled administrative practice. *Cf. Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 449 (2005) (calling "particularly dubious" the assertion that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") contained a "nonambiguous command to pre-empt [certain] tort claims" where the United States had argued to the contrary five years earlier); *see also* Oral Arg. Tr., *Bates v. Dow AgroSciences LLC*, No. 03-388, 2005 WL 148903, at *37-*39 (Jan. 10, 2005).

Instead of specific requirements, there is a presumption in favor of approval unless the FDA finds that a specifically enumerated cause for denial applies. *See* 21 C.F.R. § 814.44(d)(1) ("FDA will issue to the applicant an order approving a PMA if none of the reasons in § 814.45 for denying approval to the application applies."). If a PMA application meets the generally applicable level of safety and efficacy, the FDA is required by law to approve it—even if there are safer devices on the market and the FDA knows the device's safety is suboptimal. Indeed, the FDA did not deny *any* original PMA application during fiscal years 1993 through 2005, the last year for which annual reporting is available. A majority of the original PMA applications—including Medtronic's Evergreen Balloon Catheter—received the FDA's generic approval letter.[5]

When an application "substantially"—but not fully—meets the PMA requirements, the FDA issues an "approvable letter." 21 C.F.R. § 814.44(e). The approvable letter informs the manufacturer that its PMA application can be approved upon the submission of missing information, an inspection of its manufacturing facilities, a restriction on the sale or distribution of the device (*i.e.*, requiring distribution by licensed professionals), or an agreement to postapproval duties that typically involve continued testing, reporting, and recordkeeping. *See id.*; *see also id.* § 814.82.[6] An approvable letter imposes no

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[5] The FDA last denied an original PMA application in 1992, when it issued four denials. From 1992 through 2005, the FDA made 889 overall "approval decisions"—including 507 approvals, 248 approvable letters, 130 not approvable letters, and the 4 denials in 1992. *See* Office of Device Evaluation, *Annual Report Fiscal Year 2005*, at 36; Office of Device Evaluation, *Annual Report Fiscal Year 2004*, at 41; Office of Device Evaluation, *Annual Report Fiscal Year 2000*, at 35; Office of Device Evaluation, *Annual Report Fiscal Year 1996*, at 17. (Office of Device Evaluation Annual Reports are available at http://www.fda.gov/cdrh/ode/odeannualreports.html.)

[6] Because an approvable letter cannot dictate specific design, manufacturing, or labeling requirements (aside from requiring the prominent display of the manufacturer's proposed warning), the court below was wrong to assert that an "approvable letter" enables the FDA "to

device-specific requirements, however, and merely provides a means to facilitate approval where a substantially complete PMA application falls just shy of the minimum requirements for approval. It is a tool intended to avoid cycles of denial and resubmission; a manufacturer is free to decline the approvable letter's information requests or postapproval conditions and to resubmit an entirely new PMA application. *See id.* § 814.44(e)(2)(ii), (iii). Alternatively, where the FDA believes that an enumerated ground for denial may keep an application from being approved, it may issue a "not approvable" letter that describes the deficiency and provides the opportunity to amend the PMA application. *See id.* § 814.44(f).

Regardless of the precise path a device takes to premarket approval, the device will never need to meet a device-specific requirement. The manufacturer always has the freedom to choose any design, manufacturing method, or labeling, so long as it meets the generic minimum safety standard. Thus, in this case, the FDA "did not 'require' Medtronic's [catheter] to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493.

3. The FDA conducts the PMA process with minimal resources and suffers from conflicts of interest. The FDA receives limited funding from Congress and depends increasingly on both industry funding and advisory panel members with financial and professional interests in the

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require the device to take a particular form in order to be approved as safe and effective." Pet. App. 26a. In any event, the FDA did not issue an approvable letter in this case. *See id.* at 27a. Moreover, the court below conflated the limited "conditions of approval" that are included in an approvable letter with the FDA's power to condition PMA on a manufacturer meeting device-specific performance standards promulgated through notice-and-comment rulemaking (*see* 21 C.F.R. §§ 861.1, 861.20). *See* Pet. App. 26a-28a. No device-specific performance standards applied to Medtronic's Evergreen Balloon Catheter, and thus its PMA was not conditioned on meeting such a standard. The court below wrongly suggested that the mere *authority* to issue device-specific performance standards after notice-and-comment rulemaking preempts state tort law even where no such performance standards have been promulgated. *See id.* at 27a-28a.

device industry. As Judge Pooler recognized in dissent below, "the FDA may not have adequate resources to genuinely ensure that devices are safe or to properly and effectively reevaluate approvals as new information becomes available." Pet. App. 48a. The FDA is under enormous pressure and, as Dr. David Feigal, the former head of the FDA's Center for Devices and Radiological Health, has admitted, "'[the FDA has] to make choices about which things to work on because of shrinking resources.'" Robert J. Cohen & Scott Orr, *Often the Patient Is the Last to Know*, Star-Ledger (Newark, N.J.), Aug. 11, 2002, at 1. Congress nonetheless has reinforced its intent that the FDA license devices as quickly as possible, stating in the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, that the FDA should approve or deny a PMA application "[a]s promptly as possible," generally no later than "one hundred and eighty days after the receipt of an application." 21 U.S.C. § 360e(d)(1)(A).

Because the FDA has limited resources from congressional appropriations, it is perhaps unsurprising that the agency turns to individuals with interests in the regulated industry and, more recently, to industry financing of the regulatory process to fill the gaps in its drug and device-approval processes. In a recent survey, FDA scientists "reported significant interference with the FDA's scientific work." Union of Concerned Scientists, *Voices of Scientists at FDA: Protecting Public Heath Depends on Independent Science* at 1 (2006), *available at* http://www.ucsusa.org/scientific integrity/interference/fda-scientists-survey-summary.html. Sixty percent of the scientists surveyed knew of cases where commercial interests inappropriately influenced FDA approvals or other decisions. *See id.* at 2. One-fifth reported being "'asked explicitly by FDA decision makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials.'" *Id.*

The FDA's use of panels of "outside scientists" to advise the agency on whether to approve new medical devices

and drugs is especially plagued by conflicts of interest. A recent study of drug advisory committees found that almost one-third of the scientists on these panels "had financial interests greater than $50,000" in the company whose products they were responsible for evaluating. Jonathan D. Rockoff, *FDA Seeks to Limit Conflicts of Interest; Rules Would Restrict Outside Advisors with Industry Ties*, Baltimore Sun, Mar. 22, 2007, at 1A. For more than one-fifth of these panels, a majority of the scientists reportedly had a conflict of interest. *See* Peter Lurie et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 J. Am. Med. Ass'n 1921, 1924 (2006). On nearly three-quarters of the panels, at least one of the scientists was reported to have a conflict of interest. *See id.* A scientist who has served on FDA panels reported that those with conflicts of interest sometimes influence the panel's advice, remarking "they can be very persuasive." Rockoff, *FDA Seeks to Limit Conflicts of Interest* (internal quotation marks omitted).

The recent enactment of "user fees," through which the regulated industry now funds a significant portion of the regulatory process, has only exacerbated these conflicts of interest. *See* Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 102, 116 Stat. 1588, 1589 (codified at 21 U.S.C. § 379i). Critics argue that

> the user fees create an obvious conflict of interest. So much of the FDA budget now comes from the industry it regulates that the agency must be careful not to alienate its corporate "sponsors." FDA officials believe they remain careful but concede that user fees have imposed pressures that make review more difficult[.]

Deyo, 17 J. Am. Board Fam. Prac. at 146 (footnote omitted). In permitting the regulated industry to exercise such influence over PMA decisions, Congress could not have intended the FDA to act as the final arbiter of device

safety, foreclosing recovery by consumers subsequently injured by that industry's defective medical devices.

B. Premarket Approval Provides Negligible Continuing Oversight And Permits Design, Manufacture, And Label Changes With Either Expedited FDA Review Or No Review At All

1. Congress intended premarket approval to be a one-time licensing scheme, and therefore provided the FDA with little authority to monitor and regulate devices that have received PMA. Today, the FDA's postmarket monitoring programs are deeply flawed and rely almost exclusively on a self-reporting honor system among manufacturers. As the leading industry group has stated, device manufacture is "a continuous, iterative process," where "actual use of devices by practitioners in the clinical setting typically spurs additional refinements and improvements." Elizabeth D. Jacobson, *AdvaMed's Written Testimony on The Critical Path White Paper at Science Board to the Food and Drug Administration* 3 (Apr. 22, 2004). But, once a device is approved for marketing, the FDA exercises minimal oversight.

The near-total lack of post-PMA device regulation provided for by the original MDA demonstrates that Congress did not establish a comprehensive, continuous review process for Class III medical devices. Under the original MDA, which included the preemption provision at issue here, "device manufacturers [were] not required to notify FDA when they [became] aware of a death, injury, or hazard caused by a medical device." Statement of Franklin A. Curtis, Associate Director, Human Resources Division, United States General Accounting Office, Before the House Committee on Energy and Commerce, Subcommittee on Health and the Environment, on the Federal Regulation of Medical Devices, 98th Cong., at 5 (Feb. 24, 1984), *available at* http://archive.gao.gov/d40t12/123484.pdf. A report to Congress indicated that, while "[t]he effectiveness of FDA's regulation of medical devices depends largely on the quality of its information,"

once devices received approval there were "major deficiencies that hinder the development of a useful medical device database" to monitor for dangerous product defects. General Accounting Office, *Comptroller General's Report to Congress; Federal Regulation of Medical Devices: Problems Still To Be Overcome* at ii (GAO/HRD-85-53, 1983).

Nor do the modest improvements to the FDA's postmarket surveillance provide sufficient protection for consumers.[7] Current postmarket surveillance relies, almost entirely, on an honor system under which manufacturers are expected to forward defect and injury reports to the FDA. The FDA has admitted that the "passive nature of these systems" results in "severe underreporting." Center for Devices and Radiological Health, *Ensuring the Safety of Marketed Medical Devices* 22 (2006), *available at* http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf.

When adverse events are reported, there are "no specific rules" requiring further investigation, and "judgments about appropriate FDA responses have a considerable subjective component." *Safe Medical Devices for Children* at 125. Resource constraints "limit the agency's ability to investigate [adverse-event] reports that do not involve deaths and other high-profile events." *Id.* at 125-26. Manufacturers may report information in annual reports that are limited to a "summary and bibliography" of

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[7] Amendments to the MDA, which incorporate limited postmarket surveillance, indicate further congressional recognition that PMA provides only a screening function. As the Institute of Medicine reported:

> The statutory provisions for postmarket studies reflect Congressional awareness that the data and assessments associated with the approval or clearance of a complex medical device may leave meaningful unanswered questions about uncommon adverse events, effects in groups not studied . . . and long-term effects. To the extent that FDA encourages and accepts smaller, faster, and otherwise more limited studies to promote earlier consideration of a device for approval and reduce burdens on sponsors, more questions may remain for the postmarket period.

Institute of Medicine, *Safe Medical Devices for Children* 184 (Marilyn J. Field & Hugh Tilson eds., 2005).

information not included in the PMA application. 21 C.F.R. § 814.84(b)(2). Even where manufacturers must provide postmarket data pursuant to their PMA approval, the Institute of Medicine discovered a "disappointing picture of the agency's performance in monitoring study commitments for medical devices." *Safe Medical Devices for Children* at 192.

Even after discovering that a device for which it provided premarket approval is defective, the FDA has few tools at its disposal. Nearly all device recalls are voluntarily undertaken and directed by the manufacturer, rather than by the FDA.[8] Nor can the FDA order the recall of all PMA devices that no longer meet the threshold standards of safety and efficacy; it can do so only when it finds there is a reasonable probability that the device would cause "serious, adverse health consequences or death." 21 C.F.R. § 810.10(a). Even that limited authority is exercised rarely.

2. The FDA also has limited authority to regulate design, manufacturing, and labeling changes to a device after it receives premarket approval. First, a manufacturer can make any change after premarket approval without further FDA review if that change, in the manufacturer's judgment, does not "affect[] safety or effectiveness." 21 U.S.C. § 360e(d)(6)(A)(i). FDA regulations explain that "the burden of determining whether a [PMA] supplement is required is primarily on the PMA holder." 21 C.F.R. § 814.39(a).

Second, after premarket approval, the device maker can make manufacturing changes to a device with minimal FDA oversight. It need only give notice to the FDA that describes the change, "summarizes" any supporting data or other information, and informs the FDA that the manufacturer is adhering to good manufacturing practices. *See* 21 U.S.C. § 360e(d)(6)(A)(ii). Unless the FDA

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[8] *See* FDA, *Learn About Medical Device Recalls*, http://www.fda.gov/cdrh/recalls/learn.html (last visited Aug. 23, 2007).

objects, within 30 days of the notice, no FDA approval is needed for the manufacturing change to the device.

Finally, even for device changes, which require FDA approval when the manufacturer admits the change affects safety or effectiveness, the FDA provides a streamlined version of the original PMA process called a supplemental PMA. *See id.* § 360e(d)(6)(A)(i); *see also* 21 C.F.R. § 814.39(c) ("the information required in [a supplemental PMA application] is limited to that needed to support the change"). Certain labeling changes or changes to "quality controls or manufacturing process" can be implemented while a PMA supplemental application is still pending, so long as the manufacturer believes the changes enhance safety. 21 C.F.R. § 814.39(d). The FDA reviews a supplemental PMA application—like that submitted and approved for the Evergreen Balloon Catheter, *see* Pet. App. 3a-4a—in approximately 60 percent less time than it devotes to an original PMA. *See* Center for Devices and Radiological Health, *Office of Device Evaluation and Office of InVitro Diagnostic Device Evaluation and Safety Annual Report* (2003), *available at* http://www.fda.gov/cdrh/annual/fy2003/ode/2003.pdf.

The availability of multiple methods through which device manufacturers can update and redesign products, manufacturing methods, and device labeling forecloses a claim that PMA approval imposes any requirement upon the device. *Cf. Bates*, 544 U.S. at 451 ("Unlike the cigarette labeling law at issue in *Cipollone* [*v. Liggett Group, Inc.*, 505 U.S. 504 (1992)], which prescribed certain immutable warning statements, FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings."). The MDA provides ample opportunities for device makers to adopt different designs, manufacturing methods, and labeling, with limited and streamlined regulatory oversight. PMA approval imposes no immutable requirements upon a device manufacturer.

II. THE TORT SYSTEM PROVIDES REMEDIES AND INCENTIVES NECESSARY TO PROTECT THE PUBLIC AND TO COMPENSATE PATIENTS INJURED BY DEFECTIVE MEDICAL DEVICES THAT RECEIVED PREMARKET APPROVAL

Unlike the constrained premarket approval process, the state tort system protects consumers from dangerous medical devices. Through litigation, the public gains information about dangerous devices and wider problems within the medical device industry and with the FDA's regulatory regime. Furthermore, unlike the FDA, litigation compensates those who are injured by defective medical devices. Recent cases involving products that obtained premarket approval, such as defibrillators, heart valves, and hip implants, have highlighted defects that seriously injured consumers and demonstrated the value of litigation in informing the public and compensating victims.

A. By Uncovering Information About Defective Medical Devices, Litigation Spurs Improvements In The Medical Device Industry And The FDA

1. As this Court recognized in *Bates*, "tort suits can serve as a catalyst" to improve industry and federal regulatory practices, by "'aid[ing] in the exposure of new dangers'" and addressing their consequences. 544 U.S. at 451 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)). When "devices that do more harm than good . . . reach consumers," litigation can "help uncover previously unavailable data on adverse effects, questionable practices by manufacturers, and flaws in . . . regulatory systems." David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95, 122, 129 (2005); Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308, 308 (2007). Thus, by "dropping inflated information costs and sparking public understanding and debate," litigation

"jump-starts the market and political process," leading to better regulatory oversight and improved compliance with regulations. Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 Geo. L.J. 693, 710 (2007).

In line with this Nation's long tradition of favoring "private law enforcement" over bureaucratic regulation, litigants have broad powers to obtain information from device manufacturers, while, by statute, the FDA has relatively few discovery tools, obtaining principally what manufacturers choose to reveal (*see supra* Part IA). *See, e.g.*, Paul D. Carrington, *Recent Efforts to Change Discovery Rules: Advice for Draftsmen of Rules for State Courts*, 9 Kan. J.L. & Pub. Pol'y 456, 457-58 (2000) ("Private litigants in America thus do, and do more effectively, much of what is in other industrial states done by . . . an administrative bureaucracy."). Unlike the FDA, "litigants can demand all documents and information that ha[ve] bearing on a product's health risks," creating a much "more complete picture of the manufacturers' information on product risks than narrowly drafted self-reporting requirements do." Wagner, 95 Geo. L.J. at 700. These broad discovery and document production powers give litigation a "singular role . . . in educating the public about unscrupulous and socially dangerous business practices detrimental to the public health." Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049, 2068 (2000). By "identifying and substantiating problems" with particular medical devices, litigation alerts the public to potential dangers. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 Yale J. Health Pol'y, L. & Ethics 587, 606 (2005).

The public is also "substantially dependent on the tort system" to uncover problems within the medical device industry as a whole and with the FDA itself. Rabin, 88 Geo. L.J. at 2069. In addition to highlighting problematic industry behavior, litigation has "helped identify regulatory policies that can keep unsafe [products] on the

market" and has "exposed important limitations in the FDA information collection and dissemination procedures." Kesselheim & Avorn, 297 J. Am. Med. Ass'n at 310. For instance, the Guidant defibrillator litigation exposed the deficiencies in disclosure practices in the heart device industry, and the Sulzer hip implant litigation revealed that the FDA was failing to inspect medical device factories as frequently as the MDA requires. *See In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, MDL No. 05-1708 (DWF/AJB), Civil No. 06-25 (DWF/AJB), 2007 WL 1725289 (D. Minn. June 12, 2007); *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, 455 F. Supp. 2d 709, 712 (N.D. Ohio 2006).

By publicizing such problems, litigation spurs the "industry to improve safety, the FDA to implement more stringent controls, individuals to improve health habits, and health care providers to improve communications with patients." Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. Health Care L. & Pol'y 27, 58 (2007). Just as the Dalkon Shield litigation spurred the enactment of the MDA itself, recent litigation involving defective medical devices with premarket approval has led the medical device industry to improve its disclosure practices and safety standards, and has drawn public attention to constraints on the FDA's effectiveness. *See* Kesselheim & Avorn, 297 J. Am. Med. Ass'n at 310 (crediting the tort system with "spurring change in regulatory [and] corporate procedures, as well as extending knowledge about . . . risks by adding to the evidence available for evaluation by physicians, patients, and regulators"); *see also* Wagner, 95 Geo. L.J. at 705.

In addition to alerting the public to these dangerous devices, litigation deters misconduct by manufacturers and encourages compliance with FDA standards. The FDA's limited ability to monitor products on the market sometimes tempts manufacturers to forgo monitoring their own products or to hide problems when they discover them. *See, e.g., In re Guidant*, 2007 WL 1725289; *In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465

F. Supp. 2d 886, 889 (D. Minn. 2006). As this Court recognized in *Bates*, "[t]he long history of tort litigation . . . emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." 544 U.S. at 449-50. Because "failure to comply with FDA regulations can be very damaging to the liability case of a defendant," the threat of "liability considerably strengthens company incentives to comply with FDA regulations," thereby "confer[ring] substantial safety benefits" on the public. Steven Garber, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 125 (1993); *see also Bates*, 544 U.S. at 451 ("[p]rivate remedies that enforce federal . . . requirements would seem to aid, rather than hinder, the functioning" of federal regulations).

Removing this incentive would irrationally reward misconduct by immunizing device manufacturers from tort suits when they gained or kept their premarket approval by withholding information about defects from the FDA. *See, e.g., In re St. Jude Med., Inc. Silzone Heart Valves Prod. Liab. Litig.*, No. MDL 01-1397 JRTFLN, 2004 WL 45503, at *11 n.4 (D. Minn. Jan. 5, 2004) (immunizing manufacturers that "wrongfully withhold data from the FDA . . . cannot be what Congress had in mind when it enacted the MDA because, in its judgment, medical device manufacturers needed to be more strictly regulated"); *Lohr*, 518 U.S. at 487 (Stevens, J., plurality) (removing tort liability would have the "perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order 'to provide for the safety and effectiveness of medical devices intended for human use'") (quoting 90 Stat. 539 (preamble to MDA)).

Even when manufacturers comply with FDA regulations and act swiftly to address problems, defective medical devices can still seriously injure patients, who depend on the tort system to provide them with information about the risks they face and compensation for the harms they suffer. *See, e.g.*, Robert Cohen & J. Scott Orr, *A Glitch*

Can Kill, But Pacemaker Users Will Take That Chance, Star-Ledger (Newark, N.J.), Aug. 12, 2002, at 7 (describing how a defect in Telectronics' pacemaker led to at least 18 deaths, 30 injuries, and thousands of replacement surgeries despite the company's swift and thorough response to the problem); Price Colman, *Telectronics Defends Efforts With Defective Wire*, Rocky Mountain News, Mar. 17, 1995, at 49A.

2. The Guidant defibrillator litigation demonstrates how litigation can reveal problems and encourage improvements in the medical device industry. Guidant, a major medical device manufacturer, obtained premarket approval for what turned out to be a seriously defective heart device. In 2000, the FDA granted premarket approval to Guidant's Prizm 2 defibrillator, a device meant to restore regular heart rhythms by delivering shocks when needed. *See* Ben Harder, *Heart Device Recall: For Patients with Suspect Models, Tough Choices*, Wash. Post, June 28, 2005, at F1. In 2002, Guidant discovered that the device had two design flaws—an ineffective insulating material and inadequate wire spacing—that gave it a tendency to short-circuit and fail. *See In re Guidant*, 2007 WL 1725289, at *2. Rather than instituting a recall, Guidant designed its newer models to address the problem, without informing the FDA. *See id.* Meanwhile, it continued to sell the older models, which it knew to be flawed, "after it had fixed the problem in newer versions." Barry Meier, *F.D.A. Expanding Inquiry into Heart-Device Company*, N.Y. Times, Aug. 25, 2005, at C3.

Guidant successfully hid its knowledge of the defect for three years. Not until 2005, when a defective Guidant defibrillator caused the highly publicized death of a college student, did Guidant inform physicians and the FDA of the design flaw. The defect was responsible for at least six other deaths. *See In re Guidant*, 2007 WL 1725289, at *3; William H. Maisel, *Safety Issues Involving Medical Devices; Implications of Recent Implantable Cardioverter-Defibrillator Malfunctions*, 294 J. Am. Med. Ass'n 955, 955 (2005). A month after the publicity began, Guidant

met with the FDA and agreed to a recall. But, by that point, the faulty devices had been implanted in about 24,000 people. *See In re Guidant*, 2007 WL 1725289, at *3; Jon Kamp, *Guidant Discloses Lawsuit Tally, Says Many More Possible*, Market Watch, Feb. 22, 2006; Marc Kaufman, *More Heart Devices Malfunction; As Sophistication Has Grown, So Have Failures, FDA Reports*, Wash. Post, Sept. 17, 2005, at A7. During litigation over Guidant's conduct, documents revealed that company executives had debated warning the public about the defects earlier and had even drafted a warning letter to doctors. But the letter was not sent, and the company allowed doctors to continue implanting patients with FDA-approved devices it knew to be dangerously flawed. *See* Mark Jewell, *Guidant's Warning Letter on Defibrillators Never Sent*, Assoc. Press, Aug. 6, 2006; Barry Meier, *Inquiry Arranged by Guidant May Aid Lawsuits and Critics*, N.Y. Times, Mar. 22, 2006, at C4; Barry Meier, *Guidant Debated Device Peril*, N.Y. Times, Jan. 20, 2006, at C1.

Litigation brought Guidant's misconduct to the public's attention and encouraged improved disclosure of problems in the heart-device industry. Under pressure from the litigation, Guidant appointed an outside panel of doctors to review its disclosure practices. The panel concluded that "engineers . . . were deciding medical issues without hearing from doctors" and that Guidant failed to provide doctors "with detailed data on defibrillator failure," so that the information "had never been communicated to patients." Meier, *Inquiry Arranged by Guidant*.

These revelations led physicians and patients' groups to call for reforms to the medical device industry, including "greater transparency in post-market surveillance," better "analysis and reporting of device performance and malfunction information," and more cooperation between doctors, the FDA, and device manufacturers. Mark Carlson et al., *Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines* 1251 (2006). The criticisms led two other major heart device manufacturers, Medtronic and St. Jude, as well as

Guidant, to "heighten their scrutiny of device safety and reliability" by directly notifying patients of problems and allowing greater outside review of company safety data. Barry Meier, *Heart Device Makers Plan Enhanced Safety Reviews*, N.Y. Times, May 16, 2006, at C3. The Guidant litigation also spurred physicians to create an online database tracking defibrillator problems, so that they would no longer have to rely solely on information from device manufacturers, and patients would be able "to check on the safety and performance records" of their heart devices. Jeff Swiatek, *Doctors Seek Device-Flaw Database; Guidant's Belated Revelation of Defect in its Prizm 2 Defibrillator Spurs Call for Changes*, Indianapolis Star, May 31, 2005, at 1A.

3. The Silzone heart valve litigation shows how litigation can identify dangerously defective products that have received premarket approval and encourage the manufacturer to address the problem quickly, protecting patients. The Silzone heart valve gained premarket approval despite little proof of its safety or effectiveness. Artificial heart valves are implanted to replace patients' damaged or diseased valves. St. Jude developed the Silzone heart valve, featuring a silver coating, in the hope that silver's "anti-microbial properties" would help combat infections. *In re St. Jude*, 2004 WL 45503, at *1. The FDA gave the Silzone valve supplemental premarket approval in 1998, even though the silver-coated valve had not undergone clinical trials and had been tested in only "a small study of sheep and an 'observational study' of 20 patients for two months." Cohen & Orr, *Often the Patient Is the Last to Know*.

When the device proved to be dangerously defective, the prospect of litigation eventually encouraged the company to remove the product from the market, while the FDA took little action. After St. Jude began selling the Silzone valves to patients, clinical tests revealed that the silver coating not only did not prevent infections, but also caused the valves to leak. *See id.*; *In re St. Jude*, 2004 WL 45503, at *1. According to St. Jude, the company

"followed all the [FDA's] rules and procedures, and . . . fully informed the FDA of [its] analysis." Cohen & Orr, *Often the Patient Is the Last to Know* (internal quotation marks omitted). The then-head of the FDA's Center for Devices and Radiological Health agreed that the Silzone valve was "one of those [problems] you just don't detect until you have a larger experience." *Id.* (internal quotation marks omitted). Nonetheless, the defect was likely responsible for at least one death, a woman who died of heart failure a month after her third surgery, to replace her second defective Silzone valve, "her heart never having fully recovered from the strain of the three operations." *Id.* And at least 36,000 defective Silzone valves had been implanted in patients before St. Jude, in the face of lawsuits, issued a voluntary recall. *See id.* In response to St. Jude's voluntary recall, the FDA, which had taken no previous action, "informed St. Jude that its actions would be classified as a 'recall'" and that it considered the valves to be "defective." *In re St. Jude*, 2004 WL 45503, at *2.

4. Finally, the Medtronic defibrillator litigation demonstrates that, when device manufacturers obtain premarket approval by concealing information from the FDA, litigation helps reveal and punish their misconduct, encouraging increased compliance with FDA standards. In 2000, Medtronic redesigned the battery for its defibrillators and received supplemental premarket approval from the FDA for the changes. *See In re Medtronic*, 465 F. Supp. 2d at 889. Early in 2003, Medtronic discovered that the battery had a defect, which sometimes caused it to short-circuit. *See id.* When a battery short-circuited, it would deplete "within a few hours to a few days, after which there is a complete loss of device function." *Id.* at 890. Instead of informing doctors, patients, or the FDA of this defect, Medtronic began redesigning the battery, meanwhile obtaining FDA premarket approval for three additional defibrillator models containing the battery Medtronic knew to be defective. *See id.* at 889.

Several months after it discovered the defect, Medtronic received supplemental premarket approval for design changes to the defective battery, finally informing the FDA that the older model was prone to short-circuit. *See id.* But neither the FDA nor Medtronic instituted a recall of the faulty models or informed patients or physicians of the problem, and Medtronic continued to sell defibrillator models with the defective battery. *See id.* at 889-90. As evidence mounted that batteries in patients' defibrillators had failed, raising the threat of lawsuits, Medtronic finally warned doctors about the defect—more than two years after the company had discovered it. *See id.* at 890. Medtronic then initiated a recall of more than 100,000 defective defibrillators. *See* FDA, *Enforcement Report*, http://www.fda.gov/bbs/topics/enforce/2005/ENF00891.html (Mar. 16, 2005).

B. Litigation Compensates Victims Of Defective Medical Devices

1. A critical function of litigation is to make whole the victims of others' misconduct. *See* Mark Geistfeld, *Negligence, Compensation, and the Coherence of Tort Law*, 91 Geo. L.J. 585, 597-602 (2003). As this Court noted in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), state tort actions, "unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims." *Id.* at 64; *see also Cipollone*, 505 U.S. at 537 (Blackmun, J., concurring in the judgment in part and dissenting in part) (recognizing that "tort law has an entirely separate function—compensating victims—that sets it apart from direct forms of regulation"). When defective medical devices reach the market, whether or not the manufacturer complied with FDA regulations, patients are often seriously injured, both physically and financially. Compensation helps shield patients from the crushing financial burdens caused by defective devices. Those injured by defective devices are often left temporarily unable to work or to enjoy normal lives; some never fully recover. And, in addition to suffering physical injury, pain, and anxiety,

patients often must undergo costly and dangerous surgeries to replace the defective devices, devices that themselves may be extremely expensive. *See, e.g.*, J. Scott Orr & Robert Cohen, *Messy Plant Made Faulty Hip Joints; Late Federal Inspections, Denial Blamed in Class-action Lawsuit*, Times-Picayune, Aug. 13, 2002, at 1.

Tort law provides the only relief for patients injured by defective medical devices. The MDA contains no damages remedy; it cannot and was not intended to compensate victims of defective medical devices.[9] Congress passed the MDA to protect consumers from dangerous medical devices. *See* Pub. L. No. 94-295, 90 Stat. 539 (preamble); *see also* H.R. Conf. Rep. No. 94-1090, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1103; Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 922 n.126 (1994). Congress could not have intended the same law to strip all remedies from consumers when that protection fails. *See* Porter, 52 Food & Drug L.J. at 9 ("Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective devices, FDA does not believe that Congress intended to effect so sweeping a change without even a comment."); *see also Cipollone*, 505 U.S. at 541 (Blackmun, J., concurring in the judgment in part and dissenting in part) (noting that "[t]he Court in the past has hesitated to find pre-emption where federal law provides no comparable remedy"); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct").

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[9] The MDA has a limited provision, apparently never used, allowing the FDA to compel refunds for defective devices that present "an unreasonable risk of substantial harm" and were not "properly designed or manufactured with reference to the state of the art." 21 U.S.C. § 360h(b)(1). This provision does not provide a substitute for compensatory damages. It would have allowed, for instance, relatives of a woman who died of toxic shock syndrome caused by a defective Playtex tampon to receive only the cost of the tampon. *See O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir. 1987).

It is particularly implausible that Congress intended to leave uncompensated patients injured by defective devices that received premarket approval, because those devices often present the greatest dangers. *See* 21 U.S.C. § 360c(a)(1)(C) (Class III medical devices may present "a potential unreasonable risk of illness or injury"). Instead of creating a regulatory mechanism for compensating victims of defective medical devices, Congress left this important function to the traditional forum—the state courts. *See* Rabin, 88 Geo. L.J. at 2068, 2076 ("[R]egulatory agencies are not designed to do 'double duty' in the sense that tort law does: that is, compensating as well as creating incentives to safety.").

2. The Sulzer hip and knee implant litigation demonstrates the need for tort law to compensate patients whose lives are disrupted by the misconduct of device manufacturers. Litigation compensated patients who were injured by a serious manufacturing defect in Sulzer's artificial joints, including covering the cost of replacement surgeries and providing a fund for patients who had suffered further damages.

Sulzer's artificial hips and knees were designed to replace diseased joints, increasing mobility and relieving pain. Although the FDA granted the artificial joints premarket approval after an assertedly "rigorous review of the design, manufacturing methods, quality control procedures, clinical investigations, and labeling and marketing of the medical device," a manufacturing defect kept the implants from bonding properly with patients' bones. *In re Sulzer*, 455 F. Supp. 2d at 712; Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. Sulzer admitted in depositions that the defect resulted from unsanitary conditions in its factory. Lubricants "leaked from machinery" left a residue on the artificial joints, which Sulzer failed to discover because it never tested the devices "for oil or other contaminants." Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. The FDA had not recently inspected the factory. Although federal law requires it to inspect plants every two years, "the FDA admits that manufacturers'

plants are inspected by the agency only every five years." *Id.*

For six months, Sulzer hid its knowledge of the defect from the FDA and the public. Doctors began reporting these problems to Sulzer in June 2000. But, instead of informing the FDA or instituting a recall, Sulzer assigned "marketing and sales officials" to conduct an internal investigation. Concerned about diminishing the company's record sales of the defective products, the officials "tried to foist blame for the failed components on others," including doctors and other manufacturers. *Id.*

In December 2000, Sulzer finally informed the FDA and instituted a recall of approximately 40,000 defective hip implants. By that point, "about 26,000 had already been implanted in patients." *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, 268 F. Supp. 2d 907, 911 (N.D. Ohio 2003). With the FDA overseeing the recall, Sulzer "took some of the unimplanted recalled shells, cleaned them to remove the problem residue and sent them out to be implanted by orthopedists into patients." Victoria Colliver, *Surgical Manufacturer Under Fire; 'Recycled' Hip Implants Spell More Suffering; Some Defective Devices Replaced with Ones Previously Recalled*, S.F. Chron., June 2, 2002, at A3. About 6,000 of these reprocessed parts were implanted. *See id.* Soon, these "reprocessed" implants also began to fail, particularly in patients whose health had been compromised by previous defective Sulzer implants. *Id.*

The defective hips caused symptoms, according to Sulzer, of "severe groin pain and inability to bear weight on your leg." *In re Sulzer*, 268 F. Supp. 2d at 912. As one patient described his experience with a defective Sulzer hip implant, "it was pretty painful. After a while, I could walk, but it still hurt. I'd walk maybe 10 or 15 steps, and it'd catch. I'd almost go down—not quite, but close." Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. Other patients lost the ability to walk without crutches. *See id.* Many needed further surgery to replace the defective

implants. Some, who received defective "reprocessed" hips to replace their first defective implants, required multiple surgeries; one woman needed five hip replacement surgeries to replace defective Sulzer implants. To their dismay, patients had no choice but to continue using Sulzer components, because the replacements needed to fit the rest of their artificial hips. *See Five Implants Later, Local Woman's Hip Still Not Right: She Says the Defective Hip Implant Caused Complications that Linger*, Grand Rapid Press, Aug. 25, 2002, at C1; Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. Other patients, "medically ineligible for revision surgery," must live permanently with the pain their defective implants cause. *In re Sulzer*, 268 F. Supp. 2d at 912.

Litigation provided compensation to patients who suffered from Sulzer's misconduct. A settlement provided compensation for patients who were harmed by defective Sulzer implants, including $206,000 for each surgery a patient needed to replace a defective implant, and a $100 million fund for patients suffering extraordinary damages. *See Five Implants Later*. The litigation also convinced the company to change its manufacturing practices, including instituting "a new standard for cleanliness of products before they are sent to market." Orr & Cohen, *Messy Plant Made Faulty Hip Joints*.

CONCLUSION

The court of appeals' judgment should be reversed.

Respectfully submitted,

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